



HUMAN RESEARCH PROTECTION PROGRAM
INSTITUTIONAL REVIEW BOARDS

TO: Prof Christopher Agnew
Associate VP for Research, Regulatory Affairs

FROM: Prof Jeannie D. DiClementi
Associate Chair for Protocol Monitoring, IRB
Jeannie DiClementi

RE: Prof George McCabe request to use data
Connie Weaver Studies

DATE: August 23, 2019

I have reviewed all available documents related to IRB protocol #0710005877 “BBD Build Better Bones” (PI: Prof Connie Weaver) and Professor George McCabe’s request to use the data for additional studies. As part of this investigation, I am also privy to the remainder of Prof Weaver’s study samples, data, and documents from all of her studies.

The study in question was approved in 2007 and continued until the investigator closed it in June, 2014. The closure form signed by Prof Weaver is not available; however in her other research records, specifically the Parental Consent form, she did **not** name any other researcher as someone to whom she granted access to the data from this study. This brings to light the following:

- Only named co-investigators or key personnel may have access to study data, and
- Only the Principal Investigator may grant permission to access the data, and
- Since Prof Weaver did not specify any person(s) as having her permission to access/use such data, no one other than Prof Weaver may do so’
- Prof McCabe may not access or use these date for any studies now or in the future; Therefore his IRB application is denied.

In an investigation of Weaver study materials depository, the IRB Chair, Prof Stephen Elliott, found a significant number of non-compliances. Signed Consent Forms were stored on open shelving in an unsecured area, data files were also stored in the same area adjacent to the signed consent forms such that identification of human subjects and linkage to their personal information was possible.

In fact, the storage of sensitive and identifying documents, data, and samples was found to be grossly unorganized and in disarray, creating risk to human subjects and investigators alike, and more importantly, in clear violation of Federal and Institutional regulations.

I have therefore further determined that

- Due to evidence of a clear violation of confidentiality of subjects related to that protocol, any access to samples or data from any of Weaver’s studies by anyone is prohibited
- Because of the gross violations of subject confidentiality, data storage, and adherence to approved protocols, all samples and data related to studies with Prof Weaver as Principal or Co-Investigator must be discarded/destroyed. This is for protection of any human subjects involved with these studies.

I strongly encourage the University to mandate destruction of all materials, samples, data related to Prof Weaver studies in a timely manner to protect human research subjects and the integrity of the University.